

DECLARATION UNDER 37 CFR 1.132

I, Elliot S. Lazar, M.S., M.D., declare and say:

I am a citizen of the United States and reside at 62 Wildwood Lane, Orchard Park, NY 14127

I graduated in 1978 from the University of Pennsylvania with a Bachelor's Degree in Pre-Medical Science. In 1981 I received a Master's Degree from the Royal College of Surgeons and the SUNY Buffalo in Immunology. In 1985 I received my Doctor of Medicine from Georgetown University. In 1989, I completed my residency in Ophthalmology.

I have received numerous faculty appointments including as an Assistant Professor of Clinical Medicine at SUNY Buffalo and a Senior Instructor in the Department of Ophthalmology at the University of Rochester.

I have published numerous peer reviewed papers in the field of ophthalmology including several regarding posterior segment disease. I hold United States patents directed to ophthalmic drug delivery and surgical instrumentation. My current research is focused on drug delivery systems and interventional procedures in ophthalmology.

I am not an employee nor do I have a financial interest in Direct Contact LLC, the assignee of the present patent application.

I am familiar with United States Patent Application Serial No. 10/821718 (the '718 application) including currently pending claims 1-3, 5-14, 21-23 and 25. I have also reviewed the Office Action dated September 30, 2009.

I am familiar with the references that have been cited by the Patent Office, specifically Guy Fortier, U.S. Patent No. 5,733,563 (Fortier); Rajan Bawa, U.S. Patent No. 4,668,506 (Bawa); David J. Miller et. al., U.S. Patent Application Publication No. 2004/0071761 (Miller); and William Sponset et al., U.S. Patent Application Publication No. 2004/0198829 (Sponset).

I consider myself capable of providing the viewpoint of one of ordinary skill in the art at the time of filing of the '718 application, as well as the viewpoint of one of ordinary skill in the art when reviewing the pertinent references.

It is my understanding that independent claim 1, as amended, is directed to a polymeric hydrogel comprising a drug for the treatment of posterior segment disease wherein the drug comprises a steroid. It is also my understanding that claim 22 is directed to a polymeric hydrogel comprising a drug for the treatment of a posterior segment disease wherein the drug comprises an angiogenesis inhibitor.

In my view, one of ordinary skill in the art, at the time of filing of the '718 application, would not have considered the use of a polymeric hydrogel for the administration of a steroid or anti-angiogenesis compound (such as a VEGF antagonist) for treating posterior segment disease. This is because at the time of filing it was universally thought that effective quantities of a drug would never reach the posterior segment when placed on the surface of the eye. Topical treatments were limited to anterior segment diseases and infections that were proximal to the point of treatment. Every reference I am aware of that pre-dates the filing date of the '718 application discusses that drugs for the treatment of posterior segment disease need to be provided at the location of the posterior segment, such as by using direct injection techniques. Because of this belief that the drugs must be delivered directly to the posterior segment, no one having skill in the art would have had any expectation of success in treating posterior segment disease with a steroid or VEGF antagonist delivered via a hydrogel on the surface of the eye.

As a result of this mindset, I find the results achieved by Dr. Schultz to be truly unexpected. I also anticipate that the product embodied in the claims of the '718 application will be widely used in our field and that the use of this product will deliver great benefit to those who suffer from posterior segment disease.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing therefrom;

Further declarant saith not.

Date: March 29, 2010

Eliot S. Lazar M.D.
Eliot S. Lazar, M.S., M.D.